



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

g18284

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

September 24, 2001

WARNING LETTER
CHI-51-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Guy Ciccone, President/Owner
Nino's Enterprises, Inc.
1301 Carson Drive
Melrose Park, IL 60160

Dear Mr. Ciccone:

On August 30 and September 4, 2001, the Food and Drug Administration (FDA) conducted an inspection of your firm, as a follow-up to our inspection of April 10 and 12, 2001. These inspections found that you had, and continue to have, a serious deviation from the seafood HACCP regulations [Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)]. This deviation, which was previously brought to your attention in our letter of May 24, 2001, causes the frozen surimi and frozen lobster imported by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links on FDA's home page at www.fda.gov. Specifically:

You must have written product specifications, which are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). Your firm lacks written product specifications for the frozen surimi and frozen lobster you import from [REDACTED].

The above-identified deviation is not intended to be all-inclusive regarding deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct this deviation. Failure to promptly correct the noted deviation may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain future shipments of these products without examination until your firm is in full compliance with the seafood HACCP regulation.

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Please notify this office in writing within 15 working days from receipt of this letter of the specific steps you have taken to correct this violation, including an explanation of each step taken to prevent the recurrence of similar violations. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply relating to these concerns should be directed to James T. Karpus, Compliance Officer, Chicago District Office at the above address.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,

\s\
Raymond V. Mlecko
District Director